REMARKS

Applicant respectfully requests consideration of these remarks and examination of the pending claims 19-39 and 46, 47, 49 and 50.

Claim Amendments

Claims 19 and 30 have been amended as will be discussed below. No new matter is added by any of these amendments.

Claims 19 and 30 have been amended to include that a first longitudinal extremity of the valve body defines the valve body first end and an opposing second longitudinal extremity of the valve body defines the valve body second end. Claim 19 has also been amended to include that the valve body tapers linearly along its longitudinal extent from the valve body first end to the second end.

Rejections Under 35 U.S.C. § 102

Claims 19-24, 27, 29, and 49 were rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 6,458,153 to Bailey. Applicant respectfully traverses this rejection.

With regard to independent claim 19, Bailey fails to teach or suggest a percutaneous heart valve prosthesis comprising a valve body having a first longitudinal extremity defining a valve body first end and an opposing second longitudinal extremity defining a valve body second end with the valve body tapering linearly along its longitudinal extent from the valve body second end to the valve body first end.

Applicant notes that in the previous Office Action that the Examiner asserted that elements 20, 16 of Bailey (described as an "intermediate section" and distal anchor section respectively) constitute the valve body first end. The Examiner also asserted that element 16 of Bailey (described by Bailey as a distal anchor section) constitutes the valve body second end. Accordingly, the Examiner has considered the distal anchor section (16) to form both the valve body first and second ends. Applicant assumes this may, perhaps, have been an oversight or typographical error in the Office Action, and assume that Examiner specifically considers the intermediate section (20) to form the valve body second end and the distal anchor section (16) to form the valve body first end.

Whilst it is possible to argue that the intermediate section (20) that the Examiner asserted as constituting the valve body first end and distal anchor section (16) form sections of the valve body, they do not form ends *per se* of the valve body. More particularly and with regards to the amended claim, the first longitudinal extremity of the valve body (12) does not define the distal anchor section (16) and the longitudinally opposing second longitudinal extremity of the valve body does not define the intermediate section (20) that Examiner previously asserted constitutes the valve body second end. Further the valve body (12) of Bailey only tapers linearly across a relatively short part of its longitudinal extent defined by the transitional section (18) of the body member (12). The intermediate section (20) and distal anchor section (16) of the valve body (12) each have constant diameter annular cross-sections. This is most apparent in Figure 4 of Bailey.

Each of dependent claims 20 to 24 and 27 to 29 is patentable over Bailey at least by virtue of the fact that they are each dependent from patentable claim 19.

Claim 22 is further patentable over Bailey, which fails to teach or suggest sub-frame members of the valve body having the general form of a deltoid with each deltoid having acute-angled vertices at the valve body first and second ends.

Applicant notes that Examiner has asserted that at least the cells that comprise element 16, 22 are considered the "general form of a deltoid" and have acute angle vertices. Applicant respectfully disagrees. Claim 22 includes that the deltoid has acute-angled vertices at the valve body first and second ends, and oblique-angled vertices located between the valve body first and second ends. In contrast, the cells of Bailey comprising element 16 (being the distal anchor section 16) are each formed of two acutely angled struts (13. Bailey's element 16 does not have an acutely angled vertex at the valve body second end. Whilst one acute-angled vertex is located at one end of the valve body, the opposing acute-angled vertex would be located at the junction between the transitional section (18) and intermediate section (20) as opposed to being located at a longitudinal extremity of the valve body defining a valve body end.

Considering the cells comprising elements 22 (the proximal anchor flange (22)), it would appear that the Examiner, in rejecting claim 19, has considered the proximal anchor flange (22) to not form part of the valve body. Instead, the end of Bailey's valve body is cited as being element 20. If element 20 is considered to be the end, then the vertex of element 22 cannot be at the "end" since it extends past element 20. Otherwise, Bailey's valve body would have three "ends" in 16, 20, and 22. Claim 19 as amended includes first and second opposing longitudinal extremities. Once 16 and 20 are cited for being these longitudinal extremities, element 22 cannot be cited for showing the limitations of claim 22, since it is more "extreme" than element 20.

Further considering claim 24, Applicant submits that none of the shapes identified by the Examiner constitute a rhombus, which necessarily has all four sides of equal length. If one were to consider the shape defined by a combination of struts of a single cell of the distal anchor section (16) and transitional section (18), the struts of the transitional section (18) are significantly shorter than those of the distal anchor section (16). Similarly, if one were to consider the shape defined by the combination of struts forming a single cell of the proximal anchor flange (22) and intermediate section (20), the length of the struts of the intermediate section are significantly shorter than those of the proximal anchor flange.

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Claims 19-24, 27-28, 30-35, 38, and 49-50 were rejected under 35 USC 102(b) as anticipated by U.S. Patent Publication No. 2005/0043790 to Seguin. Applicant respectfully traverses this rejection.

With regard to independent claim 19, Seguin fails to teach or suggest a percutaneous heart valve prosthesis comprising a valve body having a first longitudinal extremity defining a valve body first end and an opposing second longitudinal extremity defining a valve body second end with the valve body tapering linearly along its longitudinal extent from the valve body second end to the valve body first end. Applicant notes that Examiner has asserted that the wider edge of valve segment 10 of Seguin (described by Seguin as a frustoconical proximal portion 10) constitutes a valve body second end and a combination of valve segments 11, 12 of Seguin (described by Seguin as a proximal cylindrical portion (11) and distal frustoconical portion (12)) form a valve body first end. As an alternative, Examiner has asserted that a combination of segments 10 and 11 or 10, 11 and 12 may constitute the valve body second end.

Whilst it is possible to argue that the distal frustoconical portion (12) forms an end section of a valve body, it does not form an end *per se* of the valve body, and the proximal cylindrical portion (11) and distal frustoconical portion (12) can certainly not together be considered to form an end of the valve body. More particularly, the longitudinal extremity of the valve body does not define the proximal cylindrical portion (11) and distal frustoconical portion (12) that Examiner asserts form the valve body first end. Further, the valve body, formed by the distal frustoconical portion (12), proximal cylindrical portion (11), and frustoconical proximal portion (10) does not taper linearly along its longitudinal extent, with only the frustoconical proximal portion (10) and distal frustoconical portion (12) tapering.

Each of dependent claims 20 through 24, 27 and 28 are patentable at least by virtue of the fact that they are each dependent on patentable claim 19.

Claim 22 is further patentable in view of Seguin as Seguin fails to teach or suggest any sub-frame members of the valve body in the general form of a deltoid having acute-angled vertices at both the valve body first and second ends. Whilst Examiner has asserted that all the cells that comprise the valve body comprise acute-angle vertices that can be considered at the first end or second end, not one of the sub-frame members is in the general form of a deltoid with acute-angled vertices at both the valve body first and second ends as required of claim 22. Claim 22 requires that each deltoid has its acute-angled vertices at the valve body first and second ends and its oblique-angled vertices located between the valve body first and second ends. This is not the case with any cell of the valve body of Seguin, with none of the cells extending from the valve body first end to the valve body second end.

Claim 27 is further patentable in view of Seguin as Seguin fails to teach or suggest a mitral valve prosthesis. Examiner has asserted that the valve of Seguin is capable of serving as a mitral valve prosthesis. Applicant respectfully disagrees. Throughout the disclosure of Seguin it is made clear that the prosthetic valve described is to be placed in a lumen of the body, and is particularly in the form of an aortic valve. See, for example, the invention title of Seguin, and the Field of the Invention at paragraph [0003]. The anatomy of a semilunar valve, such as an aortic valve, and surrounding structure located within a duct differs greatly to the anatomy of an atrioventricular valve, such as a mitral valve, and surrounding structure located in the wall dividing an atrium and ventricle. The radial forces imparted by the radially expanded stent forming the prosthesis of Seguin would not be suitable for mitral valve replacement applications, with the structure surrounding the native mitral valve orifice not being capable of supporting any significant radial expansion forces. Further, the distal cylindrical portion (14) of the prosthetic valve of Seguin, best shown in position within a duct in Figure 9, would have no application in a mitral valve replacement, as the distal cylindrical portion (14) would be left freely floating in the left atrium.

Claim 28 is further patentable in view of Seguin as Seguin fails to teach or suggest a plurality of barbs spaced about a periphery of the valve body second end. The hooks (15) of Seguin are located on the central cylindrical portion (11), not a longitudinal extremity defining the valve body second end.

With regard to claim 49, Seguin fails to teach or suggest valve elements that block blood flow in a direction through the passage of the valve body from the valve body second end to the valve body first end. The valve elements of Seguin can be clearly seen

in Figure 3 to block flow in an opposing direction, blocking flow from the first end of the valve body towards the second end of the valve body.

With regard to independent claim 30, Sequin fails to teach or suggest a plurality of barbs spaced about a periphery of the valve body second end, with a second longitudinal extremity of the valve body defining the valve body second end. As noted above in relation to claim 28, the hooks (15) are located on the central cylindrical portion (11) of the body of the stent (2) of Seguin.

Each of claims 31-35, 38 and 50 are patentable over Seguin at least by virtue of the fact that they are each dependent upon patentable claim 30.

Claim 38 is further distinguished from Seguin which, as noted above in relation to claim 27, fails to teach or suggest a mitral valve prosthesis.

Claim 50 is also further distinguished from Seguin, which fails to teach or suggest blocking a blood flow in a direction through the passage of the valve body from the valve body second (i.e., broader) end to the valve body first (i.e., narrow) end as noted above in relation to claim 49.

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Claims 19-20 and 22-26 were rejected under 35 USC 102(b) as anticipated by U.S. Patent Publication No. 2003/0014104 to Cribier. Applicant respectfully traverses this rejection.

With regards to independent claim 19, Cribier fails to teach or suggest a percutaneous heart valve prosthesis comprising a valve body having a first longitudinal extremity defining a valve body first end and an opposing second longitudinal extremity

defining a valve body second end with the valve body tapering linearly along its longitudinal extent from the valve body second end to the valve body first end.

Applicant understands that Examiner considers that the valve second end can be considered the wider side of either of the tapers of the double-tapered or hourglass configuration or, for example, Figure 3b of Cribier, and the valve first end can be considered the other side of the taper. Applicant understands that Examiner thus considers the valve body first end is located at the centre of the valve body, rather than at an end as defined. The centre of the valve body cannot be considered to be a valve body end. Amended claim 19 further clarifies that the longitudinal extremities of the valve body define the valve body first and second ends, and that the valve body tapers linearly along its longitudinal extent. This is clearly not the case with the hourglass arrangement of Cribier.

Each of claims 20 and 22-26 is patentable in view of Cribier at least by virtue of the fact that these claims are each dependent from patentable claim 19.

Claim 22 is further distinguished form the disclosure of Cribier, which fails to teach or suggest sub-frame members of the valve body having the general form of a deltoid having acute-angled vertices at the valve body first and second ends. Whilst Applicant notes that Examiner has asserted that the stent cells are of the general form of a deltoid having acute-angled vertices, none of the stent cells of the double-tapered arrangement depicted in Figures 3b have acute-angled vertices located at both the valve body first and second ends.

Claim 25 is further distinguished from the disclosure of Cribier, which fails to teach or suggest each sub-frame member further comprising a collapsible diagonal

element extending between the oblique-angled vertices of the sub-frame member. Whilst Applicant notes that Examiner has asserted that the diagonal elements (17) are diagonally inclined to block blood flow, this does not result in the diagonal elements extending between the oblique-angled vertices of any one sub-frame element. The diagonal elements (17) are not in any way located between the oblique-angled vertices of any one sub-frame member, nor do they in any way extend between such oblique-angled vertices.

The rejections under 35 USC 103.

Claims 30-38 were rejected under 35 USC 103(a) as being unpatentable over Cribier in view of U.S. Patent Publication No. 2004/0093060 to Seguin et al. Applicant respectfully traverses this rejection.

Contrary to Examiner's assertions, Cribier does not disclose all of the claim limitations of these claims except for a plurality of prongs spaced about a periphery of the valve body second end. Cribier also fails to teach or suggest a valve body having a first longitudinal extremity defining a valve body first end and a longitudinally opposing second longitudinal extremity defining a valve body second end with the valve body tapering towards the valve body first send and the valve body first end being sized to pass through a valve orifice associated with a heart valve to be replaced whilst the valve body second end is sized so as not to pass through the valve orifice.

The valve body of the Cribier prosthesis tapers from each of the ends towards the centre of the prosthesis and the valve body first and second ends are of the same size

such that there is no teaching or suggestion that one end is sized to pass through a valve orifice and the other end sized not to pass through the same valve orifice.

Further, as noted above, Seguin fails to teach or suggest provision of a plurality of barbs spaced about a periphery of a valve body second (that is, broader) end with a longitudinal extremity of the valve body defining the valve body second end. No combination of Cribier and Seguin teaches each of the limitations of independent claim 30 or any of its dependent claims 31 through 38.

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Claim 39 was rejected under 35 USC 103(a) as being unpatentable over Seguin in view of Bailey.

Contrary to Examiner's assertions, as discussed above in relation to claim 30, Cribier does not disclose all the claim limitations, except for the means of delivering the valve. No combination of Seguin and Bailey teaches each of the limitations of claim 39.

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Claim 46 was rejected under 35 USC 103(a) as unpatentable over Bailey in view of U.S. Patent Publication No. 2004/0039442 to Goar.

Contrary to Examiner's assertions, as discussed above, Bailey fails to teach or suggest a device having each of the claim limitations of claim 19.

Further, the only prosthesis of Bailey that is utilised to treat a failed or failing mitral valve is the stent valve (40) depicted in Figures 12a and 12b referred to by the Examiner. This stent valve is depicted in greater detail in Figures 7 to 11 as having a valve body member (12) having a substantially cylindrical central section and proximal and distal anchor flanges (44, 42) formed at the first and second ends of the valve body member

(12). Further, neither Bailey nor Goar suggest locating a prosthesis in the catheter with the valve body second end located between the valve body first end and the catheter first (i.e., leading) end. As noted above, the mitral valve stent (40) of Bailey is not tapered so as to distinguish between a second end and a first end of the valve body. Further, in the method depicted in Figure 20, the valve body first end is positioned between the valve body second end and the catheter first end.

No combination of Bailey and Goar teaches or suggests each of the claim elements of claim 46.

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Claim 47 was rejected under 35 USC 103(a) as unpatentable over Cribier in view of Seguin as in Claim 30 and further in view of Bailey and Goar et al.

Contrary to Examiner's assertions, as discussed above, Cribier in view of Seguin fails to teach or suggest the device of claim 30 and a method of treating a failed or failed mitral valve. Paragraph 75 of Cribier referred to by Examiner makes reference only to a mitral valve, but provides no teaching of a method of treating a mitral valve.

Further, the teachings of Bailey and Goar suffer various deficiencies as discussed above in relation to claim 46.

Accordingly, no combination of Cribier, Seguin, Bailey and Goar teaches or suggests each of the claim limitations of claim 47.

CLOSING

Applicant has amended claims 19 and 30. Examination of pending claims 19-39, 46, 47, 49 and 50 is respectfully requested.

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede any basis for rejections or objections in the Office Action. Further, with regards to the various statements made in the Office Action concerning any prior art, the teachings of any prior art are to be interpreted under the law. Applicant makes no admissions as to any prior art. The remarks herein are provided simply to overcome the rejections and objections made in the Office Action in an expedient fashion.

The undersigned welcomes a telephonic interview with the Examiner, if the Examiner believes that such an interview would facilitate resolution of any outstanding issues.

Respectfully submitted

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